Alpha Omega Inc.

A Texas Corporation

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K001520

NOV 22 2000

November 20, 2000

510(k) Summary
Alpha Omega Dual^2 Cooler-Heater

Common Name: Heater-cooler, Classification 74DWC
Classification Name: Cardiopulmonary Bypass Temperature Controller (per 21CFR 870.4250)

The Alpha Omega Dual^2 Cooler-Heater is indicated to supply temperature-controlled water to heat exchange devices (ie. . . CPB Heat Exchangers, Cardioplegia Heat Exchangers and thermal regulating system blankets) to help control a patient's temperature during cardiopulmonary bypass procedures lasting not longer than six hours. It is substantially equivalent to the Sarns TCM approved under K841402.

The intended use, mechanical systems and electrical systems of both devices are functionally equivalent. Both systems provide circulating water at a user-selected temperature used for heating or cooling a patient. In both systems, cooling is achieved by circulating water through an ice bath, and heating is accomplished by a resistance heater in the circulation loop. Temperature output is controlled by mixing valves drawing water through the heating and cooling circuits. While both systems have two individual water circulation loops, only the DCH can independently control the temperature in both circuits. Flow output, thermal performance and temperature stability of the two devices are nearly identical.

The DCH system has also been determined to have low levels of electromagnetic interference and susceptibility. The DCH has also been independently certified to comply with the UL Medical Electrical Equipment safety standards. Through these and other tests, Alpha Omega has concluded that the DCH system is at least as safe and effective as the predicate device. This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Sincerely,

L. M. King
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2000

Alpha Omega Inc.
c/o Mr. L. M. King
President
P.O. Box 669
114 Main Street
Grapeland TX 75844

Re: K001520
Trade Name: Alpha Omega Dual² Cooler-Heater
Regulatory Class: II (two)
Product Code: DWC
Dated: September 11, 2000
Received: September 13, 2000

Dear Mr. King:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN) : K001520

DEVICE NAME : Alpha Omega, Inc. Dual 2/5 Cooler-Heater

INDICATIONS FOR USE :

The Alpha Omega Dual 2/5 Cooler Heater is indicated to supply temperature-controlled water to heat exchange devices (ie. . . CPB Heat Exchangers, Cardioplegia Heat Exchangers and thermal regulating system blankets) to help control a patient=s temperature during cardiopulmonary bypass procedures lasting not longer than six hours.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001520

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K001520

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)